

## **II. Remarks**

### **A. Status of the Claims**

Claims 2 and 4 have been amended without prejudice.

New claim 19 has been added.

Support for the amended and new claims can be found throughout the specification and in the original claims.

Claims 18-25, 28-35, 36-49, and 50-52 have been previously cancelled without prejudice in response to the Restriction Requirement.

Claims 1-17 and 19 are pending, with claims 8 and 9 withdrawn from the consideration.

It is respectfully submitted that claims 1-17 and 19 are encompassed by the elected invention, and that no new matter has been added by virtue of the present amendments.

### **B. Claim Rejections- 35 U.S.C. § 102**

Claims 1-7 and 10-17 were rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 5,955,104 ("Mombberger").

The rejection is respectfully traversed.

Independent claim 1 recites a pharmaceutical formulation comprising an anionic polymer coated over a substrate comprising an opioid antagonist.

Momberger describes an oral pharmaceutical dosage form comprising pellets. *Abstract.* Each pellet contains (a) substantially inert core, (b) an active ingredient layer and (c) a coating over the active ingredient layer for retarding the release of the active ingredient from the active ingredient layer into an aqueous body fluid solvent in situ. *Id.* Both the active ingredient layer and the delay layer may contain a binder, which may be an anionic copolymer of methacrylic acid and methyl methacrylate or ethyl acrylate. *Column 4, lines 34-46.* A binder (e.g., an anionic copolymer) is included in a nonembedding amount. *Column 2, line 48.* “[A] nonembedding amount of binder means that the vast majority of the active ingredient layer is the active ingredient itself, and only so little binder is present that the active ingredient is not embedded in any embedding material or matrix of any kind, but under a microscope it visibly retains its particulate identity.” *Column 3, lines 21-27.* Momberger states that in the formulation described therein “the binder solution does **not coat** or embed the active ingredient particles.” *See column 3, lines 30-31 (emphasis added).*

Momberger therefore does not teach a pharmaceutical formulation comprising an anionic polymer coated over a substrate comprising an opioid antagonist as recited in claim 1, and thus cannot anticipate claim 1.

Claims 2-7 and 10-17 depend from claim 1 and therefore are also not anticipated by Momberger.

In response to the Examiner’s statement that Momberger discloses “the dispersed antagonist of instant claim 4” which recites that “the opioid antagonist is dispersed in matrix multiparticulates,” Applicants note that in Momberger “the active ingredient is not embedded in any embedding material or matrix of any kind, but under a microscope it visibly retains its particulate identity.” *Column 3, lines 23-27.* Momberger therefore does not teach a formulation

wherein “the opioid antagonist is dispersed in matrix multiparticulates.”

In response to the Examiner’s statement that “[t]he properties recited in instant claims 5, 6, 11, and 13-15 are inherent properties of the claimed composition,” Applicants note that “[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).” *MPEP*, section 2112. Further, “to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' ” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).” *Id.*


In the present case, the only offered support for rejection of claims 5, 6, 11, and 13-15 is a mere conclusory statement “[t]he properties recited in instant claims 5, 6, 11, and 13-15 are inherent properties of the claimed composition.” Applicants respectfully submit that this statement is insufficient to establish that “that the allegedly inherent characteristic[s] necessarily flow[] from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

For the foregoing reasons, withdrawal of the rejection is respectfully requested.

### III. CONCLUSION

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,  
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